K964673

Safety

JUN 26 1997

This 510(k) Summary of Safety & Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The device is a Class II device, System Thermal Regulating 74 DWG, Patient Warming System called the Bair Hugger® Total Temperature Management System® - Modification. The predicate device is the Bair Hugger Patient Warming System, Model 525 Blanket (K903360). The following summarizes safety issues related to skin surface warming devices and the measures to prevent these problems.

1. Summary of Safety:

A. Injuries to tissue: Cutaneous burns. Thermal injury is determined by a combination of temperature and time. Patients with ischemic limbs or extremely poor perfusion are especially susceptible to thermal injuries.

Prevention: The Bair Hugger Series 500 and 600's Maximum Heat Output (setting III at 43°C) do not provide temperatures high enough to cause burns to tissue. Performance testing demonstrated that by the time the air leaves the Bair Hugger Temperature Management Units, flows through the hose and is circulated through the inflatable Blanket placed over the patient, temperatures have dropped from 43°C to 41°C. These temperatures are well within the range of safety.[1,2]

Overtemperature condition: Bair Hugger Temperature Management Units temperature-out-of-range detection system is mechanical, using thermostats to detect over/under temperature conditions. The system triggers audible and visual alarms and shuts the blower's heating elements off when overtemperature conditions are detected.

Labeling: Labels affixed to each Bair Hugger Blanket next to the inlet port and packaged with each Bair Hugger Blanket read as follows:
"Contraindications: 1. Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury to ischemic limbs may occur.
2. Do not leave patients with poor perfusion unmonitored during prolonged warming therapy sessions."

B. Hyperthermia:

Warming treatment continued past the point of the patient reaching normothermia may eventually produce hyperthermia.[3]

Prevention: Instructions packaged with each Bair Hugger Blanket instruct the user to "Monitor the patient's temperature at least every 10 to 20 minutes."

C. Systemic Complications:

1. Prevention: Patient core temperature is continually monitored by clinicians during anesthesia with a device of their choice. The "Instructions for Use" packaged with each Bair Hugger Blanket states that patient temperature should be continually monitored with an appropriate device.

D. Other Safety Concerns:

1. Contamination. Airborne contamination from air blown intraoperatively across the surgical wound may result in airborne contamination.

   Prevention of airborne contamination: All Bair Hugger® Blankets designed for use in the operating room feature a tape barrier which prevent air from migrating toward the surgical site. Additionally, air is filtered through a 0.2 micron filter. Two studies have concluded that the Bair Hugger 500 Series Units (that have the same air output specifications and the same filter density as the Model 600) do not increase the incidence of microbial or wound contamination.[4,5]

2. Summary of Effectiveness

The Bair Hugger Model 630 Cardiac Blanket effectively provides hypothermia treatment when used as part of a system with Bair Hugger Temperature Management Units.

Performance data show that the Model 630 Cardiac Blanket delivers air temperatures in the warming mode within the same specifications as the Bair Hugger Model 525 Blankets, using the same Bair Hugger Temperature Management Units.

Conclusion

The Model 630 Cardiac Blanket is constructed of the same materials as the Model 525 Blanket and other blankets currently on the market. The intended use of the Model 630 Cardiac Blanket is identical to that of the Model 525 Blanket. Therefore, because of the similarities to the predicate device, Augustine Medical believes this Modification does not raise any new safety or effectiveness issues.

Bibliography

1. Moritz AR, Henriques FC. The Relative Importance of the Time and Surface Temperature in the Causation of Cutaneous Burns. Am J Path 23:695-720, 1947.
2. Stoll AM, Green LC. Relationship Between Pain and Tissue Damage Due to Thermal Radiation. J Apply Phys 14:373-382, 1959.
3. Genauer, MB. Postoperative Heat Stroke. Anesthesiology 7:302-309, 1946.
4. Hall, A. Bair Hugger® Warmer Does Not Increase Microbial Contamination in the Operating Room. Abstract presented at the Post Graduate Assembly, New York Society of Anesthesiologists, New York, NY, December 1991.
5. Zink, RS. Convective Warming Therapy Does Not Increase the Risk of Wound Contamination in the Operating Room. Anesthesiology 77:A1093, 1992 & Anesth Analg, 1993:76;50-3.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JUN 26 1997

Re: K964673
Augustine Medical Bair Hugger® Model 630 Cardiac Blanket
Regulatory Class: II (Two)
Product Code: 74 DWJ
Dated: April 8, 1997
Received: April 9, 1997

Dear Dr. Augustine:

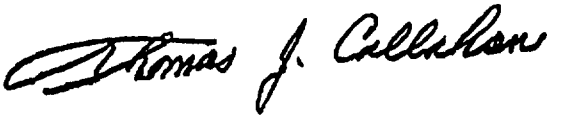
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address"dsmo@fdadr.cdrh.fda.gov."

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

870.5700 - Thermal Regulating System - Patient Warming
DWJ-II - Blanket

Indications for Use

510(k) number: K964673

Device name: The Bair Hugger® Patient Temperature Management® System - Modification: Model 630 Cardiac Blanket

Indications for use:

The Bair Hugger® Model 630 Cardiac Blanket is intended to be used to warm adult patients during cardiac surgery.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter D Lamphere

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K964673

Prescription Use X
(Per 21 CFR 801-109)

or

Over the Counter Use ____